

Minutes of Meeting
Alabama Medicaid Agency
Pharmacy and Therapeutics Committee

December 10, 2003
1:00 PM

Attendees: Jefferson Underwood, Chair; Rob Colburn, Jackie Feldman, Richard Freeman, David Herrick, A.Z. Holloway, Garry Magouirk, Ben Main, Melanie Smith, John Searcy, Louise Jones, Lisa Boothby, Brenda Gleason, Bernie Olin, Margaret Thrower

(1) Opening Remarks and Business

Jefferson Underwood: Called the meeting to order. Welcome.
Introduced new members to the Committee: David Herrick, (anesthesiologist), Jackie Feldman, (psychiatrist) and Melanie Smith, (long term care pharmacist). Also introduced Brenda Gleason and Margaret Thrower assisting with the pharmacotherapy reviews.

Reminder that the Agency's web site contains the Pharmacy and Therapeutics Committee policies and procedures, as well as the pharmacotherapy reviews.

(2) Minutes from the September 17, 2003 meeting were approved.

(3) Election of Vice-Chair for the P&T Committee: Eligibility is limited to physicians. Nomination was made for Garry Magouirk and seconded. Nominations were closed. Garry Magouirk elected by acclamation.

(4) Pharmacy Program Update was provided by Louise Jones:

Acting Commissioner is Kathy Hall, serving as Deputy Commissioner of the Programs area which included the Pharmacy program, until permanent Commissioner is named.

Kelli Littlejohn, a pharmacist, was introduced. The position is funded through the Health Information Designs (HID) contract. She is at the Medicaid office full time.

Preferred Drug List:

Skeletal Muscle Relaxants: Soft edit, since December 1, 2003.

Hard edit effective, January 5, 2004; all brand names require a Prior Authorization (PA). All generics and covered over-the-counter (OTC) drugs in that class are preferred and are available without PA. The PA form and criteria

have been updated on the web site to include this class and are available. HHD is accepting PA requests for the class in advance of the effective date.

Anxiolytics will be posted in approximately February to March 2004, undergoing a similar soft and hard edit process.

Drug classes reviewed today will be implemented in approximately March to April 2004.

The Clinical Services contract with Samford University expired November 30, 2003. Auburn University, Harrison School of Pharmacy is providing these services through December 2003. Brenda Gleason, Margaret Thrower, Bernie Olin and Lisa Boothby will be presenting the pharmacotherapy reviews today. The Invitation to Bid (ITB) for the new contract will be released in the next month.

A letter explaining the various recommendations and voting options available to the Pharmacy and Therapeutics (P&T) Committee concerning the PDI, was sent earlier to the members. These choices were stated again for the Committee (as agreed by John Scarey and Jefferson Underwood).

The P&T Committee members were reminded to please read all of the materials sent to them before the meeting and to be prepared for educated discussion. Because of the volume of material, we will not be able to read the entire reviews to the Committee. After reading through the materials, please notify the Medicaid Agency staff ahead of time if there are any issues or questions, especially if there is "missing" information (eg, supporting studies). This will give the greatest chance of being able to address the issue in a timely manner and avoid having to table issues and get behind schedule as millions of dollars are affected.

At the last meeting Ben Main asked about cost savings based on this Committee's actions. December was the first actual month of hard data based on the PDI, and since it is only the 10th of December, there is really no data available. Medicaid expects to have substantial data in about two months on claims data and can present at the next meeting.

Jackie Feldman asked about a previous issue concerning capping or limiting the number of prescriptions accepted by Medicaid? Louise Jones responded that this proposal is at the Governor's office, along with other potential program cuts. Waiting for final decision from the Governor's office. The Governor's Office is open to input regarding the program.

- (5) Oral Presentations by Manufacturers/Manufacturer's Representatives for Section I Review. Five minute verbal presentations were made on the following drugs by, or on behalf of, the following Pharmaceutical Manufacturers:

Section I, Selected Antihyperlipidemic Agents

<u>Pharmaceutical Company</u>	<u>Product</u>
Kos Pharmaceuticals	Niaspan and Advicor
Abbott	Tricor
Bristol Myers Squibb	Pravachol
Merck	Zocor
Pfizer	Lipitor
Reliant Pharmaceuticals	Lescol and Lescol XL
Andrx	Altocor

Jefferson Underwood: Reiterated rule that cost discussion has no place in these presentations or in the P&T Committee deliberations; focused on clinical superiority and safety. Cost is handled by the Agency once clinical considerations are complete.

- (6) Oral Presentations by Manufacturers/Manufacturer's Representatives for Section II Review.

Section II, Selected Antihypertension Agents

<u>Pharmaceutical Company</u>	<u>Product</u>
Schwartz Pharma	Verelan PM
Reliant Pharmaceuticals	DynaCirc, DynaCirc CR
Pfizer	Norvasc
Glaxo Smith Kline	Coreg
Reliant Pharmaceuticals	Innopran XL

Oral Presentations by Manufacturers/Manufacturer's Representatives for Section III Review.

- (7) Section III, Selected ADHD Agents

<u>Pharmaceutical Company</u>	<u>Product</u>
Celltech Americas, Inc.	Metadate CD
Novartis	Ritalin LA
Shire US Inc.	Adderall XR
Eli Lilly	Strattera
McNeil	Concerta

- (8) PHARMACOTHERAPY REVIEWS Auburn University, Harrison School of Pharmacy (Refer to full text reviews for information)

Antilipemic Agents

Presenters: Brenda Gleason, Margaret Thrower

HMG-CoA Reductase Inhibitors Single Entity Agents (AHFS Class 240608)

Jackie Feldman: Asked a clarification question on lovastatin mortality in one study (1 death in the lovastatin group, 8 deaths in the placebo group, number of participants in trial was >900 patients).

Melanie Smith: Commented that her practice is Long Term Care and 79% of her patients are on Lipitor; proven to be very effective and safe, taken without regard to meals; lowers triglycerides, LDL and increases HDL. Long Term Care is very pro Lipitor.

HMG-CoA Reductase Inhibitor Combinations (AHFS Class 240608)

Jackie Feldman: Asked how the ballot worked. Can they make a different recommendation, offer as an amendment, etc?
(These were general questions, not relating directly to these reviews.)

Jefferson Underwood: Responded that a member can make any proposal as a motion. If it is seconded, then it will be an amendment that is added to the ballot.

Miscellaneous Antilipemic Agents (AHFS Class 240692)

Niacin Single Entity Agents

Richard Freeman: He felt there is a difference in quality of life (immediate release vs. extended release niacin products). Niacin really does increase the HDL. Thinks that the timed release form should be re-reviewed once more data is available for addition to the PDL.

Brenda Gleason: Responded that we really don't have compliance data. Should take in the evening to avoid the flushing reaction. Need to pre-treat with either product (immediate release or extended release) with aspirin or NSAID.

Niacin Combination Agents

No questions or comments.

Fibric Acid Derivatives (AHFS Class 240606)

No questions or comments.

Anti-hypertensive Classes, Selected AHFS Groups

Presenters: Margaret Thrower, Bernie Olin

Overview of Hypertension

Beta-Adrenergic Blocking Agents (AHFS Class 242400)

Calcium Channel Blocking Agents (AHFS Class 242800)

Diuretics (AHFS Class 402800)

Hypotensive Agents, Miscellaneous (AHFS Class 240800)

Hypotensive Combination Agents

No questions or comments on any of the Anti-hypertensive classes.

Attention Deficit Hyperactivity Disorder Agents, Selected AHFS Groups

Presenters: Lisa Boothby, Bernie Olin

Rapid Onset, Long Duration Stimulant Agents for ADHD (AHFS Class 282000)

Jackie Feldman: Concerning Adderall XR vs. methylphenidate. Why was Adderall XR not added into the recommendation? Immediate release of each needs dosing 1-2 times daily.

Lisa Boothby: Responded that mixed amphetamine salts have longer half life therefore immediate release form can be dosed once daily, at least for school hours and hence avoid school dosing and it is available generically.

Jackie Feldman: Clinically, Adderall XR is very effective. Also, Concerta is a very different product from the other methylphenidate products available because of its extended clinical efficacy. School-age children must come home and do homework, therefore not a niche population.

Lisa Boothby: Responded that it could be a niche population because over the 12 hours of sustained serum concentrations, many children may experience anorexia, nausea, vomiting, etc. Whereas a child can take the immediate release that will last through the school day and if medication is needed after school for particular children, a dose can be supplemented at home.

Jackie Feldman: Offered a motion to add Concerta to the PDL and add one of the following: Metadate CD, Ritalin LA or Adderall XR. There was no second, so the motion failed.

A.Z. Holloway: Stated that there is a clinical difference between short-acting and long-acting amphetamine salts. He made a motion to add Adderall XR to the PDL plus a long-acting methylphenidate. Seconded by Jackie Feldman; discussion followed.

Garry Magouirk: Stated that he has used the older agents in his practice for many years and they have been very effective. Newer agents are not necessarily better, though sometimes more convenient. The Committee needs to be careful not to treat this group of drugs differently than we do other groups on the PDL.

Jackie Feldman: Thinks the emphasis is not necessarily the drug category but the vulnerable pediatric population. The children must be able to learn and avoid accidents.

Garry Magouirk: Stated that he just wants to treat all patient groups equitably.

A.Z. Holloway: Feels that extended release products provide a level of convenience and safety for this population which warrants their inclusion.

John Searcy: Suggested lumping all four products, to allow negotiation without distinguishing among them. Also, dosage form generally is not a factor to be considered for inclusion on the PDL. This was a special situation due to the affected patient population and the compliance problems posed by school attendance, which includes the drug being a controlled substance, privacy and storage issues, abuse potential etc.

Richard Freeman: Agreed. Adderall immediate release works for many patients. Has used all of these products and feels the PA system would not be an impediment if a patient needed a drug not on the PDL.

A.Z. Holloway: Following the discussion he moved to amend his motion as follows: Medicaid should work with manufacturers on cost proposals for at least one extended release medication for ADHD to include the three methylphenidate long-acting products as well as the one long-acting mixed amphetamine salts.

Jackie Feldman: Seconded the amended motion.

Motion was approved.

Ben Main: Asked if Medicaid will notify the Committee if an agreement cannot be reached?

John Searcy: Stated that if no manufacturer comes forward, Medicaid must choose at least one product.

Miscellaneous Central Nervous System Agents, Atomoxetine (AHFS Class 289200)

Jackie Feldman: Commented that her experience has found atomoxetine to be much more tolerable to patients largely due to its extended action; she also has concerns about abuse potential of the older agents. The lack of street value is an advantage for atomoxetine. She would like it to be available, but understands the lack of data.

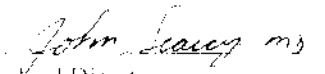
John Searcy: Stated that even if drug is not recommended for the PDL, the company can still come to the Agency and negotiate a price. Therefore, it could still be a preferred agent.

A.Z. Holloway: He has talked to mental health professionals and many use much higher than recommended doses. He uses a fair amount and has most success at higher doses. Perhaps the Agency can review again in one year. Agreed that there is a lack of data.

Jefferson Underwood: Please vote on the recommendation as presented. Make sure ballots are signed.

(9) Results of the Balloting

- A. The P&T Committee voted unanimously to accept the recommendation that Medicaid should work with the manufacturers of the brands of atorvastatin, pravastatin, and simvastatin on cost proposals so that at least one brand is selected as a preferred agent.

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Medical Director

☒ Approve

☐ Deny

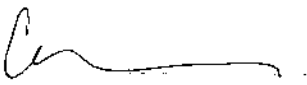
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Deputy Commissioner

☒ Approve

☐ Deny

☐ Approve with
Modification

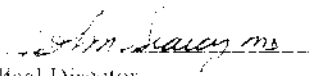
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Commissioner

☒ Approve

☐ Deny

☐ Approve with
Modification

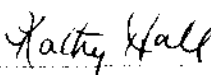
- B. The P&T Committee voted unanimously to accept the recommendation that no brand HMG-CoA Reductase Inhibitor combination product is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands.


Medical Director

☒ Approve

☐ Deny

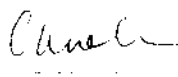
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Deputy Commissioner

☒ Approve

☐ Deny

☐ Approve with
Modification

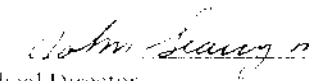

Commissioner

☒ Approve

☐ Deny

☐ Approve with
Modification

- C. The P&T Committee voted unanimously to accept the recommendation that no brand niacin single entity agent is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands.


Medical Director

☒ Approve

☐ Deny


☐ Approve with
Modification


Deputy Commissioner

☒ Approve

☐ Deny

☐ Approve with
Modification


Commissioner

☒ Approve

☐ Deny

☐ Approve with
Modification

- D. The P&T Committee voted unanimously to accept the recommendation that no brand niacin combination product is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands.

John S. [Signature]
Medical Director ☒ Approve ☐ Deny ☐ Approve with Modification

Kathy Hall
Deputy Commissioner ☒ Approve ☐ Deny ☐ Approve with Modification

[Signature]
Commissioner ☒ Approve ☐ Deny ☐ Approve with Modification

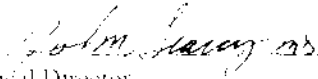
- E. The P&T Committee voted unanimously to accept the recommendation that no brand fibric acid derivative is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands.

John S. [Signature]
Medical Director ☒ Approve ☐ Deny ☐ Approve with Modification

Kathy Hall
Deputy Commissioner ☒ Approve ☐ Deny ☐ Approve with Modification

[Signature]
Commissioner ☒ Approve ☐ Deny ☐ Approve with Modification

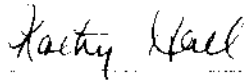
- F. The P&T Committee voted unanimously to accept the recommendation that no brand beta blocker is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands.


Medical Director

☒ Approve

☐ Deny

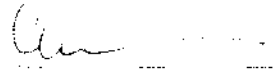
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Deputy Commissioner

☒ Approve

☐ Deny

☐ Approve with
Modification

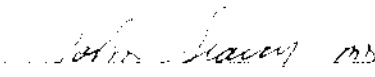

Commissioner

☒ Approve

☐ Deny

☐ Approve with
Modification

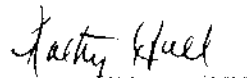
- G. The P&T Committee voted unanimously to accept the recommendation that no brand calcium channel blocker is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands.


Medical Director

☐ Approve

☐ Deny

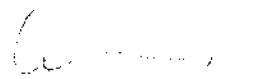
☐ Approve with
Modification


Deputy Commissioner

☒ Approve

☐ Deny

☐ Approve with
Modification


Commissioner

☒ Approve

☐ Deny

☐ Approve with
Modification

- II. The P&T Committee voted unanimously to accept the recommendation that no brand diuretic is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands.

John Slattery MD ☒ Approve ☐ Deny ☐ Approve with Modification
Medical Director

Kathy Hall ☒ Approve ☐ Deny ☐ Approve with Modification
Deputy Commissioner

[Signature] ☒ Approve ☐ Deny ☐ Approve with Modification
Commissioner

- I. The P&T Committee voted unanimously to accept the recommendation that no brand hypotensive agent is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands. No brand name version of mecamylamine or minoxidil should be placed in preferred status regardless of cost.

John Slattery MD ☒ Approve ☐ Deny ☐ Approve with Modification
Medical Director

Kathy Hall ☒ Approve ☐ Deny ☐ Approve with Modification
Deputy Commissioner

[Signature] ☒ Approve ☐ Deny ☐ Approve with Modification
Commissioner

- J. The P&T Committee voted unanimously to accept the recommendation that no brand hypotensive combination product is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands.


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Medical Director ☒ Approve ☐ Deny ☐ Approve with Modification

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Deputy Commissioner ☒ Approve ☐ Deny ☐ Approve with Modification

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Commissioner ☒ Approve ☐ Deny ☐ Approve with Modification

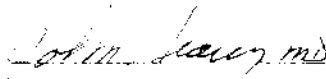
- K. The P&T Committee voted unanimously that Medicaid should work with manufacturers on cost proposals so that at least one extended release medication for ADHD, which includes the three methylphenidate long-acting products (brand name examples include Concerta, Metadate-CD, Ritalin LA) as well as the one long-acting mixed amphetamine salts (brand name examples include Adderall XR), be given preferred status.

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Medical Director ☒ Approve ☐ Deny ☐ Approve with Modification

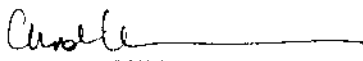
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Deputy Commissioner ☒ Approve ☐ Deny ☐ Approve with Modification

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Commissioner ☒ Approve ☐ Deny ☐ Approve with Modification

1. The P&T Committee voted unanimously to accept the recommendation that no brand of atomoxetine is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands.


Medical Director ☒ Approve ☐ Deny ☐ Approve with Modification


Deputy Commissioner ☒ Approve ☐ Deny ☐ Approve with Modification


Commissioner ☒ Approve ☐ Deny ☐ Approve with Modification

(10) New Business and Closing Remarks

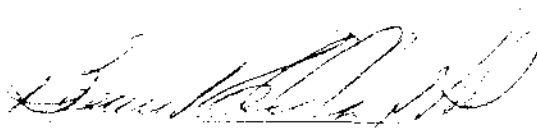
Louise Jones: Agency is looking at changing timeline for accepting cost proposals. Operate as they are posted now. Check web site in January. Medicaid thanked Jefferson Underwood for his service and leadership as Chairman.

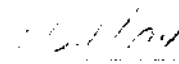
Jefferson Underwood: Thanked the Committee for their work. Thanked the four reviewers, Brenda Gleason, Lisa Boothby, Margaret Thrower and Bernie Olin for the job done on the reviews.

- (11) Louise Jones: Next meeting date was set for March. Attempt to have the meeting on the same day as the DUR Committee meeting. March 10, 17, 24 are possible. Will send out memo to establish the best date.

- (12) Meeting adjourned at 4:50pm.

Respectfully Submitted,


Bernie R. Olin, Pharm.D.


Date